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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,697	01/04/2007	Veit Krenn	BB-170	6576

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
08/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,697	KRENN ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *10-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-9) in the reply filed on May 7, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-15 are pending.

Claims 10-15, drawn to non-elected inventions are withdrawn from examination.

Claims 1-15 have been amended.

Claims 1-9 are examined on the merits, with the election of species, CDw52.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-6, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2003/0215528 A1 (filed March 6, 2003), as evidenced by Guenther et al. (Pathology-Research and Practices 201: 649-663, 2005). The publication discloses a method for treating a malignant cell, tumor and/or disease, such as solid tumors and bone malignancies, see page 17, section 0151; and pages 32 and 33. Guenther evidences it is art known cellular marker CDw52 is expressed on bone tumors, giant cell tumors and osteosarcomas, see page 656, Immunohistochemical...section, 2nd paragraph; and page 660, 2nd column, 1st full paragraph. Therapeutic formulations implemented in the method of treatment of the disclosed invention include alemtuzumab (Campath; monoclonal antibody against 21-28 kDa cell surface glycoprotein CD52), as well as chemotherapeutic agents, see page 4, sections 0027 and 0028; pages 32 and 33; and page 35, section 0152. The prior art discloses the ligand and the known characterization, properties and functions of said molecule are not seperable from the ligand, hence the ligand is specific for treatment of mGCs, macrophage-like cells and fibroblast-like cells of the tumor.

5. Claims 1-6, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2007/0037825 A1 (effective filing date July 19, 2002), as evidenced by Guenther et al. (Pathology-Research and Practices 201:

649-663, 2005). The publication discloses a method of treating solid tumors, such as bone tumors with alemtuzumab with chemotherapeutic agent, 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl]-benzamide, see page 2, sections 0018-0021. Guenther evidences it is art known cellular marker CDw52 is expressed on bone tumors, giant cell tumors and osteosarcomas, see page 656, Immunohistochemical...section, 2nd paragraph; and page 660, 2nd column, 1st full paragraph. The prior art discloses the ligand and the known characterization, properties and functions of said molecule are not seperable from the ligand, hence the ligand is specific for treatment of mGCs, macrophage-like cells and fibroblast-like cells of the tumor.

6. Claims 1-6, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2004/0191328 A1 (effective filing date December 31, 2002), as evidenced by Guenther et al. (Pathology-Research and Practices 201: 649-663, 2005). The publication discloses a method of treating neoplasms comprising solid tumors with alemtuzumab also art known as Campath® in combination with chemotherapeutic agent, gallium nitrate for the treatment of neoplasms, see abstract; section 0010 bridging pages 1 and 2; section 0031 bridging pages 3 and 4; page 3, sections 0023 and 0025; and page 4, sections 0036 and 0037. Guenther evidences it is art known cellular marker CDw52 is expressed on bone tumors, giant cell tumors and osteosarcomas, see page 656, Immunohistochemical...section, 2nd paragraph; and page 660, 2nd column, 1st full

paragraph. The disclosed ligand is specific for treatment of macrophage-like cells because the prior art notes macrophages express the CD52 antigen, see page 4, section 0036.

7. Claims 1-6, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 7,105,682 B2 (filed January 10, 2002), as evidenced by Guenther et al. (Pathology-Research and Practices 201: 649-663, 2005). The patent discloses a pharmaceutical composition comprising alemtuzumab in combination with chemotherapy for the treatment of neoplasms, such as bone cancers and osteosarcomas, see abstract; column 36, lines 9-29; column 46, lines 1-17; and column 48, lines 26-28. This disclosure, as well as Guenther evidences it is art known cellular marker CDw52 is expressed on bone tumors, giant cell tumors and osteosarcomas, see page 656, Immunohistochemical...section, 2nd paragraph; and page 660, 2nd column, 1st full paragraph. The prior art discloses the ligand and the known characterization, properties and functions of said molecule are not seperable from the ligand, hence the ligand is specific for treatment of mGCs, macrophage-like cells and fibroblast-like cells of the tumor.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2003/0215528 A1 (filed March 6, 2003), as evidenced by Guenther et al. (Pathology-Research and Practices 201: 649-663, 2005). The teachings of publication '5528 have been presented in the 102(e) rejection. The publication does not teach the method, wherein the CDw52 ligand composition is at a concentration of between 0.01 mg/kg/day and 1 mg/kg/day.

However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to provide the required *in vivo* concentration for successful cancer treatment. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the publication because it sets forth exemplary dose ranges can be established, see page 9, sections 0068-0071. Additionally, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the antibody in the recited dosages. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings well known in the art, that dosages of any pharmaceutical composition must be adjusted and optimized.

11. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2007/0037825 A1 (effective filing date July 19, 2002), as evidenced by Guenther et al. (Pathology-Research and Practices 201: 649-

663, 2005). The teachings of publication '7825 have been presented in the 102(e) rejection. The publication does not teach the method, wherein the CDw52 ligand composition is at a concentration of between 0.01 mg/kg/day and 1 mg/kg/day.

However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to provide the required *in vivo* concentration for successful cancer treatment. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the publication because it sets forth exemplary dose ranges can be established, see page 9, sections 0068-0071. Additionally, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the antibody in the recited dosages. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings well known in the art, that dosages of any pharmaceutical composition must be adjusted and optimized.

12. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 7,105,682 (filed January 10, 2002), as evidenced by Guenther et al. (Pathology-Research and Practices 201: 649-663, 2005). The teachings of the patent have been presented in the 102(e) rejection. The patent does not teach the method, wherein the CDw52 ligand composition is at a concentration of between 0.01 mg/kg/day and 1 mg/kg/day.

However, it would have been *prima facie* obvious to one of ordinary skill in the art

at the time the claimed invention was made to provide the required *in vivo* concentration for successful cancer treatment. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the publication because it sets forth exemplary dose ranges can be established, see page 9, sections 0068-0071. Additionally, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the antibody in the recited dosages. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings well known in the art, that dosages of any pharmaceutical composition must be adjusted and optimized.

13. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2004/0191328 A1 (effective filing date December 31, 2002), as evidenced by Guenther et al. (Pathology-Research and Practices 201: 649-663, 2005). The teachings of publication '1328 have been presented in the 102(e) rejection. The publication does not teach the method, wherein the CDw52 ligand composition is at a concentration of between 0.01 mg/kg/day and 1 mg/kg/day.

However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to provide the required *in vivo* concentration for successful cancer treatment. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the publication because it sets forth exemplary dose ranges can be established, see page

9, sections 0068-0071. Additionally, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the antibody in the recited dosages. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings well known in the art, that dosages of any pharmaceutical composition must be adjusted and optimized.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12 and 14-22 of copending Application No. 11/245,423 (filed October 7, 2005 and also known as U.S. Patent

Application Publication number 2006/0110396 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims read on treating a cancer that expresses cellular marker, CDw52 with a CDw52 ligand such as alemtuzumab (Campath-1H) and a chemotherapeutic agent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
25 July 2008
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643